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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,424

08/04/2006

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8336

42313 7590 08/18/2010
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EXAMINER

HOLLOMAN, NANNETTE

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/18/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,424	Applicant(s) HARRIS ET AL.	
	Examiner NANNETTE HOLLOMAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/07/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-109 is/are pending in the application.
- 4a) Of the above claim(s) 80-83 and 94-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-79 and 84-93 is/are rejected.
- 7) ☐ Claim(s) 74-79 and 84-93 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/04/06, 11/09/09, 06/07/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

Applicant's election with traverse of Group I (new claims 74-79 and 84-103) in the reply filed on June 7, 2010 is acknowledged. The traversal is on the ground(s) that the amended claims do, in fact, relate to a single inventive concept and reveal a special linking feature. This is not found persuasive because as previously asserted, the technical feature linking the claims is a composition comprising propofol and a nonionic surfactant, which fails to make a contribution over the prior art, since the feature is disclosed in Hong et al. (KP 10-2001-0055736), specifically at Example 1, p. 8; wherein the composition comprises propofol and a nonionic surfactant, i.e. Solutol HS 15™, which meets the limitation the nonionic surfactant having the structure in claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 80-83 and 94-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 7, 2010.

Information Disclosure Statement

The information disclosure statements filed August, 4, 2006, November 9, 2009 and June 7, 2010 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicant has not provided a copy of each cited foreign patent document. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 74-79 and 84-93 are objected to because of the following informalities: claim 74 recites the phrase “any other nonionic surfactant other said nonionic surfactant having said structure” which does not appear to be grammatically correct.

The acronyms “PEG” and “POE” are not defined before the first use in claim 74. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74-76 and 78-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Dennis et al. (US patent No. 6,638,537, disclosed by applicant).

Dennis et al. disclose a microemulsion delivery system for water insoluble or sparingly water soluble drugs, i.e. propofol (column 3, line 35-36) that comprise a long polymer chain surfactant component and a short fatty acid surfactant component, with the amount of each being selected to provide for spontaneous formation of thermodynamically stable microemulsion droplets, which would encompass the limitation of "self-microemulsifiable" (Abstract, reference claim 1). Dennis et al. disclose in order to make a homogeneous mixture comprising the active ingredient propofol, one needs to fix mix it with the appropriate emulsifier combination, which is being understood to meet the limitation of a "base composition"; wherein the combination has a ratio of long chain polymer surfactant to short chain fatty acid surfactant from 10 to 100 (wt./wt.) and include nonionic and anionic surfactants (column 7, lines 49-67). Dennis et al. further disclose nonionic surfactants, i.e. Tween 20 (column 8, line 37), which encompasses PEG-20 sorbitan monooleate of instant claim 76 as disclosed in the instant specification on p. 16, lines 2-3. Dennis et al. disclose a propofol "base" composition of propofol used with a microemulsion emulsifier combination of Pluronic F77®, which is a nonionic surfactant and sodium laurate, which

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is anionic, which is then mixed in the carrier liquid saline, which is isotonic to blood (column 10, lines 65-67). Therefore when TWEEN 20 is used, this encompasses the limitation of a composition not containing any other nonionic surfactant other than said nonionic surfactant having said structure of instant claim 74. Dennis et al. disclose wherein the amount of drug is from 0.1% to 1.0% (reference claim 14) and in TABLE 1 the nonionic surfactant is used at 4.0%, therefore encompassing the limitation of about 8 parts nonionic surfactant to one part propofol. Dennis et al. further disclose solutions that are clear, thermodynamically stable over time and do not support bacterial growth (column 9, lines 44-47 and Tables 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 74-76 and 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al. (US Patent No. 6,638,537, disclosed by applicant).

It is believed Dennis anticipates the instant claims, but in the event that Dennis does not disclose the specific combination of propofol and a nonionic surfactant having the structure recited in instant claim 74 (that assumption is made here for the purposes of this ground of rejection only, purely *arguendo*), the following rejection is made.

See the above disclosure of Dennis.

For the purpose of this rejection, as discussed above, it will be assumed that Dennis differs from the instant claims insofar as it does not use the specific nonionic surfactant having the structure recited in instant claim 74 in an example with propofol.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP

2144.07. It would have been obvious to have used the nonionic surfactant having the structure recited in instant claim 74, i.e. Tween 20, since it is suggested by the reference as a suitable nonionic surfactant.

2) Claims 74, 77 and 84-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al. (US Patent No. 6,638,537, disclosed by applicant) in view of Pace et al. (US Patent No. 6,726,919).

Dennis is discussed above and differs from the instant claims insofar as it does not disclose a self-microemulsifying composition comprising a water-immiscible solvent, i.e. ethyl oleate.

Pace et al. disclose micromatrices or microdroplets of a dispersion comprising propofol with a diluent that can dissolve the propofol at all temperatures, i.e. ethyl oleate and alpha-tocopherol (column 13, lines 9-10 and 35-36-column 14, lines 10-11, 22 and 55-57); wherein the compositions are stable as microemulsions in the presence of an antimicrobial agent for at least six months. Pace et al. also disclose the composition further comprises a non-ionic surfactant, i.e. polyoxy-ethylene sorbitan esters which meets the limitation of the structure of instant claims 74 and 80 (column 15, lines 49-52 and 59-60).

Pace et al. differs from the instant claims insofar as it does not disclose a self-microemulsifiable anhydrous composition.

It would have been obvious to have used solvents, i.e. ethyl oleate and alpha-tocopherol in the formulation of Dennis motivated by the desire to use a solvent that can dissolve propofol at all temperatures as disclosed by Pace et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/N. H./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612